MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) PROGRAM

ANNUAL ACTIVITY REPORT

October 2020 through September 2021
(FY2021)

Michigan Department of Health & Human Services
GRETCHEN WHITMER, GOVERNOR | ELIZABETH HERTEL, DIRECTOR

http://www.michigan.gov/con

MDHHS is an Equal Opportunity Employer, Services and Program Provider

TABLE OF CONTENTS

EXECUTIVE SUMMARY

One of the Michigan Department of Health and Human Services (MDHHS or Department) duties under Part 222 of the Public Health Code, MCL 333.22221(b), is to report to the Certificate of Need (CON) Commission annually on the Department's performance under this Part. This is the Department's 33rd report to the Commission and covers the period beginning October 1, 2020, through September 30, 2021 (FY 2021). Data contained in this report may differ from prior reports due to updates subsequent to each report's publishing date.

Administration

The Department through its Policy, Planning and Operational Support Administration provides support for the CON Commission (Commission) and its Standard Advisory Committees (SACs). The Commission is responsible for setting review standards and designating the list of covered services. The Commission may utilize a SAC to assist in the development of proposed CON review standards, which consists of a 2/3 majority of experts in the subject area. Further, the Commission, if determined necessary, may submit a request to the Department to engage the services of consultants or request the Department to contract with an organization for professional and technical assistance and advice or other services to assist the Commission in carrying out its duties and functions.

The Department, through its CON Evaluation Section, manages and reviews all incoming Letters of Intent, applications and amendments. These functions include determining if a CON is required for a proposed project as well as providing the necessary application materials, when applicable. In addition, the Section is responsible for monitoring implementation of approved projects, as well as the compliance with the terms and conditions of approvals.

During FY 2021, the Department has continued to make process improvements in both the Policy and Evaluation Sections.

The Evaluation Section promptly put in place a streamlined, electronic process for filing Emergency CON applications to assist health care providers statewide in planning and implementing the bed surge plans to adequately treat patients impacted by COVID-19 pandemic in Michigan, and tirelessly worked with other Governmental agencies and health care organizations to make the processes successful. Due to these efforts, the Department was able to approve numerous Emergency CON applications with an average review period of three (3) days that put in place additional beds at healthcare facilities statewide and continued to assist providers during these challenging times. The CON staff also volunteered to work on the COVID-19 email box and COVID-19 Hotline to help answer questions from Michigan citizens during the COVID-19 pandemic in Michigan. The Department completed statewide compliance review of all facilities providing Surgical and Air Ambulance services. The Section also facilitated webinars to provide up-to-date information on revised CON standards, application processes and CON annual survey reporting requirements.

The Policy Section assisted the Commission to make the necessary modifications to the CON Review standards to better reflect practice, improve quality, and add clarity to the standards; revised the maintenance volumes to better reflect current practice for CT Scanners; updated NICU and Special Newborn Nursing Services Standards to better reflect current practice and allowed the use of telemedicine technology for prearranged consultative agreements; developed a new bed need methodology to better reflect the need for Nursing Home and HLTCU beds; added language that allows for annualizing data if the application is utilizing an MRI List where the reporting period is impacted by a public health epidemic; updated the special pool beds for Psychiatric Beds and Services; and updated Cardiac Catheterization Services to better reflect current practice.

These initiatives have greatly increased the availability of CON information and data to improve and streamline the review process, better inform policy makers and enhance community

knowledge about Michigan's healthcare system.

CON Required

In accordance with MCL 333.22209, a person or entity is required to obtain a Certificate of Need, unless elsewhere specified in Part 222, for any of the following activities:

- Acquire an existing health facility or begin operation of a health facility.
- Make a change in the bed capacity of a health facility.
- Initiate, replace, or expand a covered clinical service.
- Make a covered capital expenditure.

CON Application Process

To apply for a CON, the following steps must be completed:

- Letter of Intent filed and processed prior to submission of an application.
- CON application filed on appropriate date as defined in the CON Administrative Rules
- Application reviewed by the Evaluation Section.
- Issuance of Proposed Decision by the Policy, Planning and Legislative Services Administration
    - Appeal if applicant disagrees with the Proposed Decision issued.
- Issuance of the Final Decision by the MDHHS Director.

There are three types of CON review: nonsubstantive, substantive individual, and comparative. The Administrative Rules for the CON program establish timelines by which the Department must issue a proposed decision on each CON application. The proposed decision for a nonsubstantive review must be issued within 45 days of the date the review cycle begins, 120 days for substantive individual, and 150 days for comparative reviews.

FY 2021 in Review

In FY 2021, there were 396 Letters of Intent received resulting in 309 applications filed for CON review and approval. In addition, the Department received 57 amendments to previously approved applications. In total, the Department approved 258 proposed projects resulting in approximately $1,380,328,632 of new capital expenditures into Michigan's healthcare system. The Department also surveyed 1,094 facilities and collected statistical data.

As required by Administrative Rules, the Department was timely in processing Letters of Intent, pending CON applications and issuing its decisions on pending applications. These measures, along with the other information contained in this report, aid the Commission in its duties as set forth in Part 222 of the Public Health Code.

During FY2021, the CON Commission revised the review standards for Computed Tomography (CT) Scanner Services, Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services, Nursing Home and Hospital Long-Term-Care Unit Beds (NH-HLTCU), Magnetic Resonance Imaging (MRI) Services, Psychiatric Beds and Services, and Cardiac Catheterization Services.

This report is filed by the Department in accordance with MCL 333.22221(f). The report presents information about the nature of these CON applications and decisions, as well as the Commission's actions during the reporting period. Several tables include benchmarks for timely processing of applications and issuing decisions as set forth in the CON Administrative Rules. Note that the data in the report represents some applications that were carried over from last fiscal year while others may be carried over into next fiscal year.

HISTORICAL OVERVIEW OF MICHIGAN'S CERTIFICATE OF NEED PROGRAM

1972 Legislation was introduced in the Michigan legislature to enact the Certificate of Need (CON) program. The Michigan CON program became effective on April 1, 1973.

1974 Congress passed the National Health Planning and Resources Development Act (PL 93-641) including funding incentives that encouraged states to establish a CON program. The purpose of the act was to facilitate recommendations for a national health planning policy. It encouraged state planning for health services, manpower, and facilities. And, it authorized financial assistance for the development of resources to implement that policy. Congress repealed PL 93-641 and certificate of need in 1986. At that time, federal funding of the program ceased and states became totally responsible for the cost of maintaining CON.

1988 Michigan's CON Reform Act of 1988 was passed to develop a clear, systematic standards development process and reduce the number of services requiring a CON.

Prior to the 1988 CON Reform Act, the Department found that the program was not serving the needs of the state optimally. It became clear that many found the process to be excessively unclear and unpredictable. To strengthen CON, the 1988 Act established a specific process for developing and approving standards used in making CON decisions. The review standards establish how the need for a proposed project must be demonstrated. Applicants know before filing an application what specific requirements must be met.

The Act also created the CON Commission. The CON Commission, whose membership is appointed by the Governor, is responsible for approving CON review standards. The Commission also has the authority to revise the list of covered clinical services subject to CON review. However, the CON sections inside the Department are responsible for day-to-day operations of the program, including supporting the Commission and making decisions on CON applications consistent with the review standards.

1993 Amendments to the 1988 Act required ad hoc committees to be appointed by the Commission to provide expert assistance in the formation of the review standards.

2002 Amendments to the 1988 Act expanded the CON Commission to 11 members, eliminated the previous ad hoc committees, and established the use of Standard Advisory Committees or other private consultants/organizations for professional and technical assistance.

Present The CON standards now allow applicants to reasonably assess requirements for approval, before filing an application. As a result, there are far fewer appeals of Department decisions. Moreover, the 1988 amendments appear to have reduced the number of unnecessary applications, i.e., those involving projects for which a need cannot be demonstrated.

The standards development process now provides a public forum and involves organizations representing purchasers, payers, providers, consumers, and experts in the subject matter. The process has resulted in CON review standards that are legally enforceable, while assuring that standards can be revised promptly in response to the changing healthcare environment.

ADMINISTRATION OF THE CERTIFICATE OF NEED PROGRAM

Commission The Commission is an 11-member body. The Commission, appointed by the Governor and confirmed by the Senate, is responsible for approving CON review standards used by the Department to make decisions on individual CON applications. The Commission also has the authority to revise the list of covered clinical services subject to CON review. Appendix I is a list of the CON Commissioners for FY2021.

NEWTAC The New Technology Advisory Committee is a standing committee responsible for advising the Commission on the new technologies, including medical equipment and services that have not yet been approved by the federal Food and Drug Administration for commercial use.

SAC A Standards Advisory Committee (SAC) may be appointed by and report to the CON Commission. The SACs advise the Commission regarding creation of, or revisions to the standards. The Committees are composed of a 2/3 majority of experts in the subject matter and include representatives of organizations of healthcare providers or professionals, purchasers, consumers, and payers.

MDHHS The Michigan Department of Health and Human Services is responsible for administering the CON program and providing staffing support for the Commission. This includes promulgating applicable rules, processing and rendering decisions on applications, and monitoring and enforcing the terms and conditions of approval. These functions are within the Policy and Legislative Administration.

Policy Section The Policy Section within the Administration provides professional and support staff assistance to the Commission and its committees in the development of new and revised standards. Staff support includes researching issues related to specific standards, preparing draft standards, and performing functions related to both Commission and Committee meetings.

Evaluation Section The Evaluation Section, also within the Administration, has operational responsibility for the program, including providing assistance to applicants prior to and throughout the CON process. The Section is responsible for reviewing all Letters of Intent and applications as prescribed by the Administrative Rules. Staff determines if a proposed project requires a CON. If a CON is required, staff identifies the appropriate application forms for completion by the applicant and submission to the Department. The application review process includes the assessment of each application for compliance with all applicable statutory requirements and CON review standards, and preparation of a Program Report and Finance Report documenting the analysis and findings. These findings are used by the Director to make a final decision to approve or deny a project.

In addition to the application reviews, the Section reviews requests for amendments to approved CONs as allowed by the Rules. Amendment requests involve a variety of circumstances, including changes in how an approved project is financed and authorization for cost overruns. The Section is also responsible for monitoring the implementation of approved projects, as well as the long-term compliance with the terms and conditions of approvals.

The Section also provides the Michigan Finance Authority (MFA) with information when healthcare entities request financing through MFA bond issues and Hospital Equipment Loan Program (HELP) loans. This involves advising on whether a CON is required for the item(s) that will be bond financed.

CERTIFICATE OF NEED PROCESS

The following discussion briefly describes the steps an applicant follows in order to apply for a Certificate of Need.

Letter of Intent (LOI) — An applicant must file an LOI with the Department and, if applicable, the regional CON review agency. The CON Evaluation Section identifies for an applicant all the necessary application forms required based on the information contained in the LOI.

Application — On or before the designated application date, an applicant files an application with the Department and the regional review agency, if applicable. The Evaluation Section reviews an application to determine if it is complete. If not complete, additional information is requested. The review cycle starts after an application is deemed complete or received in accordance with the Administrative Rules.

Review Types and Time Frames — There are three review types: nonsubstantive, substantive individual and comparative. Nonsubstantive reviews involve projects such as replacement of covered equipment or changes in ownership that do not require a full review. Substantive individual reviews involve projects that require a full review but are not subject to comparative review as specified in the applicable CON review standards. Comparative reviews involve situations where two or more applicants are competing for a resource limited by a CON review standard, such as hospital and nursing home beds. The maximum review time frames for each review type, from the date an application is deemed complete or received until a proposed decision is issued, are: 45 days for nonsubstantive, 120 for substantive individual and 150 days for comparative reviews. The comparative review time frame includes an additional 30-day period for determining if a comparative review is necessary. Whenever this determination is made, the review cycle begins for comparative reviews.

Review Process — The Evaluation Section reviews the application. Each application is reviewed separately unless part of a comparative review. Each application review includes a program and finance report documenting the Department's analysis and findings of compliance with the statutory review criteria, as set forth in Section 22225 of the Public Health Code and the applicable CON review standards.

Proposed Decision — The Policy and Legislative Administration in which the Evaluation Section resides issues a proposed decision to the applicant within the required time frame. This decision is binding unless reversed by the Department Director or appealed by the applicant. The applicant must file an appeal within 15 days of receipt of the proposed decision if the applicant disagrees with the proposed decision or its terms and conditions. In the case of a comparative review, a single decision is issued for all applications in the same comparative group.

Final Decision — If the proposed decision is not appealed, a final decision is made by the Director of the Department in accordance with MCL 333.22231. If a hearing on the proposed decision is requested, the final decision by the Director is not issued until completion of the hearing and any filing of exceptions to the proposed decision by the Michigan Administrative Hearing System. A final decision by the Director may be appealed to the applicable circuit court.

LETTERS OF INTENT

The CON Administrative Rules, specifically Rule 9201, provides that Letters of Intent (LOI) must be processed within 15 days of receipt. Processing an LOI includes entering data in the management information system, verifying historical facility information, and obtaining proof of authorization to do business in Michigan. This information determines the type of review for the proposed project, and the Department then notifies the applicant of applicable application forms to be completed.

Table 1 provides an overview of the number of LOIs received and processed in accordance with the above-referenced Rule.

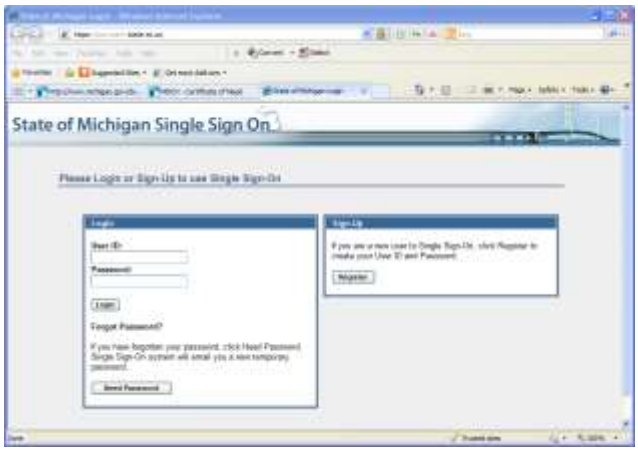
TABLE 1
LETTERS OF INTENT RECEIVED AND PROCESSED WITHIN 15 DAYS
FY2017 - FY2021

	LOIs Received	Processed within 15 Days	Percent Processed within 15 Days	Waivers Processed*
FY2017	341	340	99%	24
FY2018	371	370	99%	73
FY2019	365	363	99%	79
FY2020	420	418	99%	42
FY2021	396	394	99%	37

* Waivers are proposed projects that do not require CON review, but an LOI was submitted for Department's guidance/confirmation.

In FY 2021, LOIs were processed in a timely manner as required by Administrative Rule and available for public viewing on the online application system. The online system allows for faster processing of LOIs and subsequent applications by the Evaluation Section, as well as modifying these applications by applicants when needed.

In 2006, Michigan became the first state to have an online application and information system. Today 100% of all LOIs and applicable applications are submitted online.



http://www.mi.gov/con

TYPES OF CERTIFICATE OF NEED APPLICATION REVIEWS

The Administrative Rules also establish three types of project reviews: nonsubstantive, substantive individual, and comparative. The Rules specify the time frames by which the Bureau (Evaluation Section) must issue its proposed decision related to a CON application. The time allowed varies based on the type of review.

Nonsubstantive

Nonsubstantive reviews involve projects that are subject to CON review but do not warrant a full review. The following describes types of projects that are potentially eligible for nonsubstantive review:

- Acquire an existing health facility
- Replace a health facility within the replacement zone and below the covered capital expenditure

- Add a host site to an existing mobile network/route that does not require data commitments
- Replace or upgrade a covered clinical equipment
- Acquire or relocate an existing freestanding covered clinical service

The Rules allow the Bureau (Evaluation Section) up to 45 days from the date an application is deemed complete to issue a proposed decision. Reviewing these types of proposed projects on a nonsubstantive basis allows an applicant to receive a decision in a timely fashion while still being required to meet current CON requirements, including quality assurance standards.

Substantive Individual

Substantive individual review projects require a full review but are not subject to comparative review and not eligible for nonsubstantive review. An example of a project reviewed on a substantive individual basis is the initiation of a covered clinical service such as Computed Tomography (CT) scanner services. The Bureau (Evaluation Section) must issue its proposed decision within 120 days of the date a substantive individual application is deemed complete or received.

Comparative

Comparative reviews involve situations where two or more applications are competing for a limited resource such as hospital or nursing home beds. A proposed decision for a comparative review project must be issued by the Bureau (Evaluation Section) no later than 120 days after the review cycle begins. The cycle begins when the determination is made that the project requires comparative review. According to the Rules, the Department has the additional 30 days to determine if, in aggregate, all of the applications submitted on a window date exceed the current need. A comparative window date is one of the three dates during the year on which projects subject to comparative review must be filed. Those dates are the first working day of February, June, and October.

Section 22229 established the covered services and beds that were subject to comparative review. Pursuant to Part 222, the CON Commission may change the list subject to comparative review.

Figure 1 delineates services/beds subject to comparative review.

FIGURE 1 *Services/Beds Subject to Comparative Review in FY2021*	
Neonatal Intensive Care Unit	Nursing Home/HLTCU Beds
Hospital Beds	Nursing Home Beds for Special Population Groups
Psychiatric Beds	Psychiatric Beds for Special Population Groups
Transplantations	

Note: See individual CON review standards for more information.

Table 2 shows the number of applications received by the Department by review type.

TABLE 2
APPLICATIONS RECEIVED BY REVIEW TYPE
FY2017 - FY2021

	FY2017	FY2018	FY2019	FY2020	FY2021
Nonsubstantive*	186	154	132	118	191
Substantive Individual	89	142	72	80	84
Comparative	0	0	6	36	8**
TOTALS	275	296	210	234	283

** Includes 6 swing bed applications; does not include Emergency CONs.*
*** Excludes remand review after appeal for FY2020 nursing home comparative applications.*

Table 3 provides a summary of applications received and processed in accordance with Rule 9201. The Rule requires the Evaluation Section to determine if additional information is needed within 15 days of receipt of an application. Processing of applications includes: updating the management information system, verifying submission of required forms, and determining if other information is needed in response to applicable Statutes and Standards.

TABLE 3
APPLICATIONS RECEIVED AND PROCESSED WITHIN 15 DAYS
FY2017 - FY2021

	FY2017	FY2018	FY2019	FY2020	FY2021
Applications Received	275	296	210	234	283
Processed within 15 Days	272	295	210	234	282
Percent Processed within 15 Days	99%	99%	100%	100%	99%

Note: Includes swing bed applications; does not include Emergency CONs.

Table 4 provides an overview of the average number of days taken by the Evaluation Section to complete reviews by type.

TABLE 4
AVERAGE NUMBER OF DAYS IN REVIEW CYCLE BY REVIEW TYPE
FY2017- FY2021

	FY2017	FY2018	FY2019	FY2020	FY2021
Nonsubstantive	41	36	37	42	37
Substantive Individual	116	102	114	98	105
Comparative	N/A	N/A	94	112	122*

Note: Average review cycle accounts for extensions requested by applicants.
** Excludes remand review days after appeal, for FY2020 nursing home comparative applications.*

EMERGENCY CERTIFICATES OF NEED

Table 5 shows the number of emergency CONs issued. The Department is authorized by Section 22235 of the Public Health Code to issue emergency CONs when applicable. Rule 9227 permits up to 10 working days to determine if an emergency application is eligible for review under Section 22235. Although it is not required by Statute, the Bureau (Evaluation Section) attempts to issue emergency CON decisions to the Director for final review and approval within 10 days from receipt of request. In FY2021 the Bureau issued the 26 emergency CON decisions within an average of 3 days.

TABLE 5
EMERGENCY CON DECISIONS ISSUED
FY2017 - FY2021

	FY2017	FY2018	FY2019	FY2020	FY2021
Emergency CONs Issued	0	0	0	105	26
Percent Issued within 10 Working Days	N/A	N/A	N/A	105	26

**Emergency CON application was submitted but withdrawn before a decision was to be issued.*

PROPOSED DECISIONS

Part 222 establishes a 2-step decision making process for CON applications that includes both a proposed decision and final decision. After an application is deemed complete and reviewed by the Evaluation Section, a proposed decision is issued by the Bureau (Evaluation Section) to the applicant and the Department Director according to the timeframes established in the Rules.

Table 6 shows the number of proposed decisions by type, issued within the applicable timeframes set forth in the Administrative Rules 325.9206 and 325.9207: 45 days for nonsubstantive, 120 days for substantive individual, and 150 days for comparative reviews, or any requested extension(s) to the review cycle.

TABLE 6
PROPOSED DECISIONS ISSUED
FY2017- FY2021

	Nonsubstantive		Substantive Individual		Comparative	
	Issued	Issued on Time	Issued	Issued on Time	Issued	Issued on Time
FY2017	167	100%	99	100%	0	N/A
FY2018	174	100%	107	100%	0	N/A
FY2019	123	100%	98	100%	4	100%
FY2020	119	100%	83	100%	34	100%
FY2021	173	100%	58	100%	34	100%

Table 7 compares the number of proposed decisions by decision type made.

TABLE 7
COMPARISON OF PROPOSED DECISIONS BY DECISION TYPE
FY2017- FY2021

	Approved	Approved w/ Conditions	Disapproved	Percent Disapproved	TOTAL
FY2017	205	61	0	0%	266
FY2018	214	65	2	0.7%	281
FY2019	162	62	2	0.8%	226
FY2020	156	64	16	7%	236
FY2021	150	92	29	9%	271

Note: Not all proposed decisions issued in a given year will have a final decision in the same year.

If a proposed decision is disapproved, an applicant may request an administrative hearing that suspends the time frame for issuing a final decision. After a proposed disapproval is issued, an applicant may also request that the Department consider new information. The Administrative Rules allow an applicant to submit new information in response to the areas of noncompliance identified by the Department's analysis of an application and the applicable Statutory requirements to satisfy the requirements for approval.

FINAL DECISIONS

The Director issues a final decision on a CON application following either a proposed decision or the completion of a hearing, if requested, on a proposed decision. Pursuant to Section 22231(1) of the Public Health Code, the Director may issue a decision to approve an application, disapprove an application, or approve an application with conditions or stipulations. If an application is approved with conditions, the conditions must be explicit and relate to the proposed project. In addition, the conditions must specify a time period within which the conditions shall be met, and that time period cannot exceed one year after the date the decision is rendered. If approved with stipulations, the requirements must be germane to the proposed project and agreed to by the applicant.

This section of the report provides a series of tables summarizing final decisions for each of the review thresholds for which a CON is required. It should be noted that some tables will not equal other tables, as many applications fall into more than one category.

Table 8 and **Figure 2** display the number of final decisions issued.

FIGURE 2
FY 2021 FINAL DECISIONS ISSUED BY HEALTH SERVICE AREAS

Note: Figure 2 does not include 1 out-state decision.

TABLE 8 *FINAL DECISIONS ISSUED FY2017- FY2021*	
FY2017	272
FY2018	276
FY2019	224
FY2020	314
FY2021	287

Table 9 summarizes final decisions by review categories defined in MCL 333.22209(1) and as summarized below:

Acquire, Begin Operation of, or Replace a Health Facility
Under Part 222, a health facility is defined as a general hospital, hospital long-term care unit, psychiatric hospital or unit, nursing home, freestanding surgical outpatient facility (FSOF), and health maintenance organization under limited circumstances. This category includes projects to construct or replace a health facility, as well as projects involving the acquisition of an existing health facility through purchase or lease.

Change in Bed Capacity
This category includes projects to increase in the number of licensed hospital, nursing home, or psychiatric beds; change the licensed use; and relocate existing licensed beds from one geographic location to another without an increase in the total number of beds.

Covered Clinical Services
This category includes projects to initiate, replace, or expand a covered clinical service: neonatal intensive care services, open heart surgery, extrarenal organ transplantation, extracorporeal shock wave lithotripsy, megavoltage radiation therapy, positron emission tomography, surgical services, cardiac catheterization, magnetic resonance imaging services, computed tomography scanner services, and air ambulance services.

Covered Capital Expenditures
This category includes capital expenditure projects in the clinical area of a licensed health facility that is equal to or above the threshold set forth in Part 222. Typical examples of covered capital expenditure projects include construction, renovation, or the addition of space to accommodate increases in patient treatment or care areas not already covered. In 2020, the covered capital expenditure threshold was $3,375,000 and as of January 1, 2021, the covered capital expenditure threshold was increased to $3,425,000. The threshold is updated in January of every year.

TABLE 9 *FINAL DECISIONS ACTIVITY CATEGORY FY2017 - FY2021*					
Approved	**FY2017**	**FY2018**	**FY2019**	**FY2020**	**FY2021**
Acquire, Begin, or Replace a Health Facility	47	56	27	36	43
Change in Bed Capacity	26	40	40	136	54
Covered Clinical Services	167	180	164	160	163
Covered Capital Expenditures	65	32	36	58	53
Disapproved					
Acquire, Begin, or Replace a Health Facility	0	1	2	2	23
Change in Bed Capacity	0	0	0	2	28
Covered Clinical Services	0	0	0	0	1
Covered Capital Expenditures	0	0	0	1	25

Note: Totals above may not match Final Decision totals because one application may include multiple categories.

Table 10 provides a comparison of the total number of final decisions and total project costs by decision type.

TABLE 10 *COMPARISON OF FINAL DECISIONS BY DECISION TYPE FY2017 - FY2021*				
	Approved	**Approved with Conditions**	**Disapproved**	**Totals**
Number of Final Decisions				
FY2017	208	64	0	272
FY2018	210	65	1	276
FY2019	162	62	2	226
FY2020	147	167	2	316
FY2021	168	90	29	287
Total Project Costs				
FY2017	$ 1,069,086,777	$ 307.391,790	$ 0	$ 1,376,478,567
FY2018	$1,590,933,280	$544,275,880	$200,000,000	$2,335,209,160
FY2019	$828,424,031	$494,288,355	$174,010,658	$1,496,723,044
FY2020	$2,023,996,054	$292,720,764	$22,323,062	$2,339,039,880
FY2021	$1,092,194,095	$288,134,537	$562,706,545	$1,943,035,177

Note: Final decisions include emergency CON applications.

In FY2021, 29 CON applications received final decision of disapproval from the Department. One (1) project was to begin operation of a new hospital with 117 beds in Limited Access Area-6 (Oakland County). The other applications were to begin operation of new nursing homes or add new beds within the following Counties – Kalamazoo, Kent, Livingston, Monroe, Oakland and Washtenaw.

CERTIFICATE OF NEED ACTIVITY SUMMARY COMPARISON

Table 11 provides a comparison for various stages of the CON process.

TABLE 11 CON ACTIVITY COMPARISON FY2017 - FY2021				
	Number of Applications	**Difference from Previous Year**	**Total Project Costs**	**Difference from Previous Year**
Letters of Intent Processed				
FY2017	341	(23%)	$1,864,251,305	22%
FY2018	397	16%	$2,660,753,511	43%
FY2019	365	(8%)	$2,876,054,374	(8%)
FY2020	420	15%	$1,861,451,187	(35%)
FY2021	396	(6%)	$2,443,097,718	31%
Applications Submitted				
FY2017	275	(14%)	$1,598,240,431	29%
FY2018	296	8%	$2,575,451,177	61%
FY2019	212	(28%)	$1,237,316,450	(52%)
FY2020	339	61%	$2,507,922,695	3%
FY2021	309	(9%)	$1,703,931,501	(32%)
Final Decisions Issued				
FY2017	272	(10%)	$1,376,478,567	5%
FY2018	276	2%	$2,335,209,160	70%
FY2019	225	(18%)	$1,333,240,369	(43%)
FY2020	316	40%	$2,339,039,880	75%
FY2021	287	(9%)	$1,944,965,809	(17%)

Note: Applications submitted, and final decisions Issued include Emergency CONs and swing bed applications.

AMENDMENTS

The Rules allow an applicant to request to amend an approved CON for projects that are not complete. The Department has the authority to decide when an amendment is appropriate or when the proposed change is significant enough to require a separate application. Typical reasons for requesting amendments include:

- **Cost overruns -** The Rules allow the actual cost of a project to exceed the approved amount by 15 percent of the first $1 million and 10 percent of all costs over $1 million. Fluctuations in construction costs can cause projects to exceed approved amounts.

- **Changes in the scope of a project -** An example is the addition of construction or renovation required by regulatory agencies to correct existing code violations that an applicant did not anticipate in planning the project or a change in covered clinical equipment.

- **Changes in financing -** Applicants may decide to pursue a financing alternative better than the financing that was approved in the CON.

- **Change in construction start date** – The Rules allow an Applicant to request an extension to start construction/renovation for an approved project.

Table 12 provides a summary of amendment requests received by the Department and the time required to process and issue a decision. Rule 9413 permits that the review period for a request to amend a CON-approved project be no longer than the original review period.

TABLE 12
AMENDMENTS RECEIVED AND DECISIONS ISSUED
FY2017 - FY2021

	FY2017	FY2018	FY2019	FY2020	FY2021
Amendments Received	67	80	92	57	57
Amendment Decisions Issued	68	75	90	66	57
Percent Issued within Required Time Frame	100%	100%	100%	100%	100%

NEW CERTIFICATE OF NEED CAPACITY

Table 13 provides a comparison of existing covered services, equipment and facilities already operational to new capacity approved in FY 2021. Seventy-five (75) of the 238 CON approvals in FY 2021 were for new or additional capacity. The remaining approvals were for replacement equipment, relocation of existing services, acquisitions, renovations and other capital expenditures.

TABLE 13
COVERED CLINICAL SERVICES AND BEDS
FY2021

Covered Clinical Services/Beds	Existing Sites	Existing Units/Beds	New Sites	New Units/Beds
Air Ambulances	14	17	1	1
Cardiac Catheterization Services	60	244	1	6
Primary PCI	1	N/A	0	0
Elective PCI	15	N/A	0	0
Open Heart Surgical Services	34	N/A	1	0
Surgical Services	283	1484	5	18
CT Scanners Services	275	419	2	7
MRI Services	307	322	7	3
PET Services	104	28	4	2
Lithotripsy Services	93	11	8	0
MRT Services	70	126	1	1
Transplant Services	6	N/A	N/A	N/A
Hospitals	185	26,102	0	165
NICU Services	21	650	0	3
SCN Services	17	104	0	0
Extended Care Services Program (Swing Beds)	32	297	6	55
Nursing Homes/HLTCU	480	49,251	2	95
Psychiatric Hospitals/Units	72	3,143	5	327
Psychiatric Flex Beds	4	46	0	0

Note: The source for the existing site and unit/bed information for Table 13 was the 2020 CON Annual Survey, and CON applications approved but not yet operational. Table 13 does not account for projects expired, facilities closed, and beds delicensed and returned to the various bed pools since the last survey period for CY 2020. New sites include mobile host sites for CT, Lithotripsy, MRI and PET services.

COMPLIANCE ACTIONS

Table 14 shows there were 314 projects requiring follow-up for FY 2021 based on the Department's Monthly Follow-up/Monitoring Report as shown below.

TABLE 14
FOLLOW UP AND COMPLIANCE ACTIONS
FY2017 - FY2021

	FY2017	FY2018	FY2019	FY2020	FY2021
Projects Requiring 1-yr Follow-up	303	272	226	225	314
Approved CONs Expired	78	118	83	87	95
Compliance Orders Issued	54	48	30	65	95

Note: CONs are expired due to non-compliance with terms and conditions of approval or when the recipient has notified the Department that either the approved-project was not implemented or the site is no longer providing the covered service/beds. Compliance Orders include orders issued by the Department under MCL 333.22247, settlement agreements offered or remedies for non-compliance. The Department completed a Statewide Compliance Review of Surgical and Air Ambulance Services. Other compliance issues ordered included individual facility's compliance issues related to MRI, PET, and Cardiac Catheterization Services.

ANALYSIS OF CERTIFICATE OF NEED PROGRAM FEES AND COSTS

Section 20161(3) sets forth the fees to be collected for CON applications. Figure 3 shows the application fees based on total projects costs and additional fees per the new fee structure, effective October 15, 2013, approved under House Bill No. 4787.

FIGURE 3
CURRENT CON APPLICATION FEES

Total Project Costs	**CON Application Fee**
$0 to $500,000	$3,000
$500,001 to $3,999,999	$8,000
$4,000,000 to $9,999,999	$11,000
$10,000,000 and above	$15,000
Additional Fee Category	**Additional Fee**
Complex Projects (i.e. Comparative Review, Acquisition or replacement of a licensed health facility with two or more covered clinical services.)	$3,000
Expedited Review - Applicant Request	$1,000
Letter of Intent (LOI) Resulting in a Waiver	$500
Amendment Request to Approved CON	$500
CON Annual Survey	$100 per Covered Clinical Service

Table 15A analyzes the number of applications by fee assessed.

TABLE 15A NUMBER OF CON APPLICATIONS BY FEE FY2017 – FY2021					
CON Fee	FY2017	FY2018	FY2019	FY2020	FY2021
$ 0*	1	1	0	106	32
$3,000	95	123	76	78	84
$8,000	93	86	87	79	101
$11,000	42	30	23	25	58
$15,000	44	54	25	53	34
TOTAL	275	292	211	341	309

Note: Table 15A may not match fee totals in Table 16, as Table 16 accounts for refunds, overpayments, MFA funding, etc.

** No fees are required for emergency CON and swing beds applications.*

Table 15B analyzes the fees collected for the additional fee categories. More than one fee category may be assessed for one application.

TABLE 15B NUMBER OF ADDITIONAL CON APPLICATION FEES FY2017 – FY2021					
CON Fee Category	FY2017	FY2018	FY2019	FY2020	FY2021
Complex Project	9	2	5	36	7
Expedited Review	31	52	29	41	26
LOI Waiver*	23	77	79	45	37
Amendment*	56	80	92	57	57
Annual Survey (Facilities)	1,056	1052	1066	1067	1094

**Note: Some waivers and amendments do not require a fee based on the type of change requested.*

Table 16 provides information on CON program costs and source of funds.

TABLE 16 CON PROGRAM COST AND REVENUE SOURCES FOR FY2017– FY2021					
	FY2017	FY2018	FY2019	FY2020*	FY2021
Program Cost	$1,972,166	$2,382,030	$2,114,316	$2,109,705	$2,463,147
Fees/Funding	$2,293,095	$2,607,045	$1,990,861	$2,447,531	$2,520,217
Fees % of Costs	100%+	100%+	94%	100%+	100%+

Source: MDHHS Budget and Finance Administration.

**Under Public Act 169 of 2020, for the fiscal year ending September 30, 2020, only, $3,000,000 of the money in the Certificate of Need program was transferred to and deposited into the general fund.*

CERTIFICATE OF NEED COMMISSION ACTIVITY

During FY2021, the CON Commission revised the review standards for Computed Tomography (CT) Scanner Services, Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services, Nursing Home and Hospital Long-Term-Care Unit Beds (NH-HLTCU), Magnetic Resonance Imaging (MRI) Services, Psychiatric Beds and Services, and Cardiac Catheterization Services.

The revisions to the CON Review Standards for CT Scanner Services received final approval by the CON Commission on September 17, 2020 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective November 9, 2020. The final language changes include the following:

- Section 2(1)(m): New definition - "CT-GUIDED ABLATION" MEANS ANY INVASIVE PROCEDURE PERFORMED IN A CT SCANNER REQUIRING CT GUIDANCE OF A NEEDLE OR OTHER DEVICE TO TREAT A TUMOR.
- Section 2(1)(n): New definition - "CT-GUIDED NON-ABLATION PROCEDURE" MEANS ANY INVASIVE PROCEDURE, REQUIRING CT GUIDANCE, PERFORMED IN THE CT SCANNER OTHER THAN CT-GUIDED ABLATIONS.
- Section 14(4): Revised the maintenance volumes as follows.
    - (a) The approved CT scanners shall be operating AS FOLLOWS FOR THE SECOND 12-MONTH PERIOD AFTER BEGINNING OPERATION OF THE CT SCANNER, AND ANNUALLY THEREAFTER, EXCEPT FOR THOSE SCANNERS EXEMPT UNDER APPLICABLE SECTIONS:
    - (i) An average of 7,500 CT equivalents per fixed scanner PER YEAR UNLESS ONE OF THE FOLLOWING HAS BEEN MET:
    - (A) 5,000 CT EQUIVALENTS PER FIXED SCANNER PER YEAR FOR CT SERVICES WITH ONE FIXED SCANNER.
    - (B) 2,500 CT EQUIVALENTS PER FIXED SCANNER PER YEAR FOR CT SERVICES WITH ONE FIXED SCANNER LOCATED OUTSIDE THE 20-MILE RADIUS FROM THE NEXT CLOSEST FIXED CT SERVICE.
    - (C) A HOSPITAL, WITH ONE FIXED SCANNER, LICENSED UNDER PART 215 OF THE CODE THAT OPERATES AN EMERGENCY ROOM THAT PROVIDES 24-HOUR EMERGENCY CARE SERVICES AS AUTHORIZED BY THE LOCAL MEDICAL CONTROL AUTHORITY TO RECEIVE AMBULANCE RUNS SHALL NOT HAVE A MINIMUM ANNUAL VOLUME REQUIREMENT FOR PURPOSES OF THIS SECTION.
    - (D) A FREESTANDING SURGICAL OUTPATIENT FACILITY (FSOF), WITH ONE FIXED SCANNER, LICENSED UNDER PART 208 OF THE CODE THAT OPERATES AN EMERGENCY ROOM THAT PROVIDES 24-HOUR EMERGENCY CARE SERVICES AS AUTHORIZED BY THE LOCAL MEDICAL CONTROL AUTHORITY TO RECEIVE AMBULANCE RUNS SHALL NOT HAVE A MINIMUM ANNUAL VOLUME REQUIREMENT FOR PURPOSES OF THIS SECTION.
    - (E) AN OFF-CAMPUS EMERGENCY DEPARTMENT OF A HOSPITAL, LICENSED UNDER PART 215 OF THE CODE, WITH ONE FIXED SCANNER, THAT HAS OBTAINED PROVIDER-BASED STATUS UNDER 42 CFR 413.65, THAT IS AVAILABLE FOR TREATING EMERGENCY PATIENTS 24 HOURS A DAY, 7 DAYS A WEEK, AND AUTHORIZED BY THE LOCAL MEDICAL CONTROL

AUTHORITY TO RECEIVE AMBULANCE RUNS SHALL NOT HAVE A MINIMUM ANNUAL VOLUME REQUIREMENT FOR PURPOSES OF THIS SECTION.
    - (ii) 1,500 CT equivalents per mobile scanner.
- Section 16(4): Defines what the conversion factor is based on.
- Section 16(5): Added additional factors.
- Other technical edits.

The revisions to the CON Review Standards for NICU and Special Newborn Nursing Services received final approval by the CON Commission on December 10, 2020 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective March 19, 2021. The final language changes include the following:

- Section 2(1)(v): Revised definition - "Special care nursery services" or "SCN services" means provisions of services for infants with problems that are expected to resolve rapidly and who would not be anticipated to need subspecialty services on an urgent basis. These services ARE:
    - (i) care for infants born greater than or equal to 32 weeks gestation and/or weighing greater than or equal to 1,500 grams;
    - (ii) enteral tube feedings;
    - (iii) cardio-respiratory monitoring to document maturity of respiratory control or treatment of apnea;
    - (iv) extended care following an admission to a neonatal intensive care unit for an infant not requiring ventilatory support;
    - (v) continuous positive airway pressure AND HIGH FLOW NASAL CANNULA (HFNC); AND
    - (vi) mechanical ventilation for a brief duration (UP TO 24 hours).
    FOR BABIES REQUIRING MECHANICAL VENTILATION EXCEEDING 24 HOURS, SCNS SHALL REQUEST TRANSFER TO A NICU BY THE 24TH HOUR OF MECHANICAL VENTILATION. Referral to a higher level of care should ALSO occur for all infants who need pediatric surgical or medical subspecialty intervention. Infants receiving transitional care or being treated for developmental maturation may have formerly been treated in a neonatal intensive care unit in the same hospital or another hospital. For purposes of these standards, SCN services are special newborn nursing services.
- Section 2(1)(w): Added new definition - "TELEMEDICINE" MEANS THE USE OF AN ELECTRONIC MEDIA TO LINK PATIENTS WITH HEALTH CARE PROFESSIONALS IN DIFFERENT LOCATIONS. TO BE CONSIDERED TELEMEDICINE UNDER THIS SECTION, THE HEALTH CARE PROFESSIONAL MUST BE ABLE TO EXAMINE THE PATIENT VIA A HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996, PUBLIC LAW 104-191 COMPLIANT, SECURE INTERACTIVE AUDIO, VIDEO, OR BOTH, TELECOMMUNICATIONS SYSTEM, OR THROUGH THE USE OF STORE AND FORWARD ONLINE MESSAGING.
- Section 7(2): Modified the high occupancy methodology to bring it more in line with other CON review standards.
- Section 9(1)(b)(i): Revised based on the revision in the definition of SCN services.
- Section 12: Revised based on the revision in the definition of SCN services and the addition of telemedicine.
- Other technical edits.

The revisions to the CON Review Standards for NH-HLTCU received final approval by the CON Commission on December 10, 2020 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective March 19, 2021. The final language changes include the following:

- Section 2(1)(d): Added definition that clarifies the current calculation - "AVERAGE OCCUPANCY RATE" IS CALCULATED AS FOLLOWS:
  - (i) CALCULATE THE NUMBER OF PATIENT DAYS, FOR WHICH VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT, DURING THE MOST RECENT, CONSECUTIVE 12-MONTH PERIOD, AS OF THE DATE OF THE APPLICATION.
  - (ii) CALCULATE THE TOTAL LICENSED BED DAYS FOR THE SAME 12-MONTH PERIOD AS IN (i) ABOVE BY MULTIPLYING THE TOTAL LICENSED BEDS AND CON APPROVED BUT NOT YET LICENSED BEDS BY THE TOTAL NUMBER OF DAYS THEY WERE LICENSED OR CON APPROVED BUT NOT YET LICENSED.
  - (iii) DIVIDE THE NUMBER OF PATIENT DAYS CALCULATED IN (i) ABOVE BY THE TOTAL LICENSED BED DAYS CALCULATED IN (ii) ABOVE, THEN MULTIPLY THE RESULT BY 100.
- Previous Section 2(1)(u): Removed "occupancy rate" definition as it's no longer used.
- Section 3(2): Developed a new bed need methodology to better reflect the need.
- Section 6(1)(e) and (2)(f): No longer needed with the new bed need methodology.
- Section 7: Clarified the replacement language when transferring patients.
- Other technical edits.

The revisions to the CON Review Standards for MRI Services received final approval by the CON Commission on March 18, 2021 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective May 28, 2021. The final language changes include the following:

- Section 2(1)(ll): Defines "Public Health Epidemic" - "PUBLIC HEALTH EPIDEMIC" MEANS AN EPIDEMIC IDENTIFIED AND CONTROLLED PURSUANT TO MCL 333.2253(1) OR MCL 333.2453(1), OR AN EPIDEMIC OR PANDEMIC AS DECLARED BY THE CENTERS FOR DISEASE CONTROL (CDC) OR THE WORLD HEALTH ORGANIZATION (WHO).
- Section 4(5)(c): Allows for the annualizing of procedure data if the application is utilizing an MRI List where the reporting period is impacted by a public health epidemic when replacing an existing fixed MRI service and its unit(s) to a new site.

  Each existing MRI unit to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 14 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department unless one of the following requirements OF SUBSECTION (i), (ii), OR (iii) are met: IF THE APPLICATION IS UTILIZING AN MRI LIST WHERE THE DEPARMENT DETERMINES THAT THE REPORTING PERIOD IS IMPACTED BY A PUBLIC HEALTH EPIDEMIC AND THE FACILITY WAS PREVENTED BY LAW FROM OPERATING AT FULL CAPACITY DUE TO THE PUBLIC HEALTH EPIDEMIC, THE APPLICANT MAY ANNUALIZE THEIR MRI ADJUSTED PROCEDURES AND SHALL INCLUDE ONLY THOSE MONTHS AND PROCEDURES PERFORMED WHEN THE FACILITY WAS NOT PREVENTED BY LAW FROM OPERATING AT FULL CAPACITY DUE TO THE PUBLIC HEALTH EPIDEMIC. IF USING

ANNUALIZED DATA, THE APPLICANT SHALL SUBMIT AN AFFIDAVIT CONFIRMING THE MONTHS THAT THE FACILITY WAS PREVENTED BY LAW FROM OPERATING AT FULL CAPACITY DUE TO THE PUBLIC HEALTH EPIDEMIC.

- Section 5(2): Allows for the annualizing of procedure data if the application is utilizing an MRI List where the reporting period is impacted by a public health epidemic when expanding an MRI service.

  IF THE APPLICANT IS APPLYING FOR EXPANSION, AND THE APPLICATION IS UTILIZING AN MRI LIST WHERE THE DEPARMENT DETERMINES THAT THE REPORTING PERIOD IS IMPACTED BY A PUBLIC HEALTH EPIDEMIC, AND THE FACILITY WAS PREVENTED BY LAW FROM OPERATING AT FULL CAPACITY DUE TO THE PUBLIC HEALTH EPIDEMIC, THE APPLICANT MAY ANNUALIZE THEIR MRI ADJUSTED PROCEDURES AND SHALL INCLUDE ONLY THOSE MONTHS AND PROCEDURES PERFORMED WHEN THE FACILITY WAS NOT PREVENTED BY LAW FROM OPERATING AT FULL CAPACITY DUE TO THE PUBLIC HEALTH EPIDEMIC. IF USING ANNUALIZED DATA, THE APPLICANT SHALL SUBMIT AN AFFIDAVIT CONFIRMING THE MONTHS THAT THE FACILITY WAS PREVENTED BY LAW FROM OPERATING AT FULL CAPACITY DUE TO THE PUBLIC HEALTH EPIDEMIC.
- Section 6(4): Allows for the annualizing of procedure data if the application is utilizing an MRI List where the reporting period is impacted by a public health epidemic when acquiring an MRI service.

  IF THE APPLICANT IS APPLYING FOR ACQUISITION, AND THE APPLICATION IS UTILIZING AN MRI LIST WHERE THE DEPARMENT DETERMINES THAT THE REPORTING PERIOD IS IMPACTED BY A PUBLIC HEALTH EPIDEMIC, AND THE FACILITY WAS PREVENTED BY LAW FROM OPERATING AT FULL CAPACITY DUE TO THE PUBLIC HEALTH EPIDEMIC, THE APPLICANT MAY ANNUALIZE THEIR MRI ADJUSTED PROCEDURES AND SHALL INCLUDE ONLY THOSE MONTHS AND PROCEDURES PERFORMED WHEN THE FACILITY WAS NOT PREVENTED BY LAW FROM OPERATING AT FULL CAPACITY DUE TO THE PUBLIC HEALTH EPIDEMIC. IF USING ANNUALIZED DATA, THE APPLICANT SHALL SUBMIT AN AFFIDAVIT CONFIRMING THE MONTHS THAT THE FACILITY WAS PREVENTED BY LAW FROM OPERATING AT FULL CAPACITY DUE TO THE PUBLIC HEALTH EPIDEMIC.
- Section 20(1): Update the dates.

The revisions to the CON Review Standards for Psychiatric Beds and Services received final approval by the CON Commission on March 18, 2021 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective May 28, 2021. The final language changes include the following:

- Section 3(1) of the Addendum: Update the base numbers based on the new percentages.
- Section 17(1): Update the dates.

The revisions to the CON Review Standards for Cardiac Catheterization Services received final approval by the CON Commission on June 17, 2021 and were forwarded to the Governor and

legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective September 22, 2021. The final language changes include the following:

- Section 2(1): Added and moved/modified definitions as follows:
  - (b) "APPLICANT" MEANS ONE OF THE FOLLOWING TYPES OF FACILITIES:
  - (i) AMBULATORY SURGICAL CENTER (ASC) WHICH IS DEFINED AS ANY DISTINCT ENTITY CERTIFIED BY MEDICARE AS AN ASC UNDER THE PROVISIONS OF TITLE 42, PART 416 THAT OPERATES EXCLUSIVELY FOR THE PURPOSE OF PROVIDING SURGICAL SERVICES TO PATIENTS NOT REQUIRING HOSPITALIZATION.
  - (ii) FREESTANDING SURGICAL OUTPATIENT FACILITY (FSOF) WHICH IS DEFINED AS A HEALTH FACILITY LICENSED UNDER PART 208 OF THE CODE. IT DOES NOT INCLUDE A SURGICAL OUTPATIENT FACILITY OWNED AND OPERATED AS A PART OF A LICENSED HOSPITAL SITE. A FREESTANDING SURGICAL OUTPATIENT FACILITY IS A HEALTH FACILITY FOR PURPOSES OF PART 222 OF THE CODE.
  - (iii) Hospital WHICH IS DEFINED AS a health facility licensed under Part 215 of the Code. *[Merged/modified from previous subsection (r)]*.
  - (g) "CARDIAC IMPLANTABLE ELECTRONIC DEVICE (CIED) PROCEDURE" MEANS IMPLANTATION OF TRANSVENOUS SINGLE AND DUAL CHAMBER PACEMAKER, TRANSVENOUS SINGLE AND DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDS), AND ALL GENERATOR CHANGES.
  - (t) "EXCESS PROCEDURE EQUIVALENTS" MEANS THE NUMBER OF PROCEDURE EQUIVALENTS PERFORMED BY AN EXISTING CARDIAC CATHETERIZATION SERVICE IN EXCESS OF 1200 PER CARDIAC CATHETERIZATION LABORATORY AND 300 PCI SESSIONS (810 PROCEDURE EQUIVALENTS) PER SERVICE. THE NUMBER OF CARDIAC CATHETERIZATION LABORATORIES USED TO COMPUTE EXCESS PROCEDURE EQUIVALENTS SHALL INCLUDE BOTH EXISTING AND APPROVED BUT NOT YET OPERATIONAL CARDIAC CATHETERIZATION LABORATORIES. IN THE CASE OF A CARDIAC CATHETERIZATION SERVICE THAT OPERATES OR HAS A VALID CON TO OPERATE MORE THAN ONE LABORATORY AT THE SAME SITE, THE TERM MEANS NUMBER OF PROCEDURE EQUIVALENTS IN EXCESS OF 1200 MULTIPLIED BY THE NUMBER OF CARDIAC CATHETERIZATION LABORATORIES AT THE SAME SITE. FOR EXAMPLE, IF A CARDIAC CATHETERIZATION SERVICE OPERATES, OR HAS A VALID CON TO OPERATE, 2 CARDIAC CATHETERIZATION LABORATORIES AT THE SAME SITE, THE EXCESS PROCEDURE EQUIVALENTS IS THE NUMBER THAT IS IN EXCESS OF 2400 PROCEDURE EQUIVALENTS AND IN EXCESS OF 300 PCI SESSIONS (810 PROCEDURE EQUIVALENTS).
- Section 4(2): New requirements to allow for an FSOF to initiate diagnostic cardiac catheterization and elective PCI.
  - (2) AN APPLICANT FSOF PROPOSING TO INITIATE DIAGNOSTIC CARDIAC CATHETERIZATION AND ELECTIVE PCI SHALL DEMONSTRATE THE FOLLOWING:
  - (a) THE APPLICANT HAS IDENTIFIED AT LEAST ONE INTERVENTIONAL CARDIOLOGIST TO PERFORM THE DIAGNOSTIC CARDIAC CATHETERIZATIONS AND PCI PROCEDURES WHO HAS PERFORMED AT

LEAST 50 PCI SESSIONS ANNUALLY AS THE PRIMARY OPERATOR DURING THE MOST RECENT 24-MONTH PERIOD PRECEDING THE DATE THIS APPLICATION WAS SUBMITTED TO THE DEPARTMENT. THE INTERVENTIONAL CARDIOLOGIST SHALL HAVE COMPLETED AN INTERVENTIONAL CARDIOLOGY FELLOWSHIP TRAINING PROGRAM, BE BOARD CERTIFIED IN INTERVENTIONAL CARDIOLOGY, HAVE PERFORMED A TOTAL OF AT LEAST 250 PCI SESSIONS AS THE PRIMARY OPERATOR, AND HAVE A MINIMUM OF 2 YEARS EXPERIENCE AT AN ATTENDING LEVEL.

- (b) THE APPLICANT HAS IDENTIFIED NURSING AND TECHNICAL CATHETERIZATION LABORATORY STAFF THAT ARE EXPERIENCED IN HANDLING ACUTELY ILL PATIENTS AND COMFORTABLE WITH INTERVENTIONAL EQUIPMENT AND HAVE ACQUIRED EXPERIENCE IN DEDICATED INTERVENTIONAL LABORATORIES AT AN OHS HOSPITAL. COMPETENCY SHALL BE DOCUMENTED ANNUALLY.
- (c) THE APPLICANT HAS IDENTIFIED CARDIAC CARE UNIT NURSES WHO ARE ADEPT IN HEMODYNAMIC MONITORING AND IABP MANAGEMENT. COMPETENCY SHALL BE DOCUMENTED ANNUALLY.
- (d) THE LABORATORY OR LABORATORIES WILL BE EQUIPPED WITH OPTIMAL IMAGING SYSTEMS, RESUSCITATIVE EQUIPMENT, AND INTRA-AORTIC BALLOON PUMP (IABP) SUPPORT, AND STOCKED WITH A BROAD ARRAY OF INTERVENTIONAL EQUIPMENT. THE LABORATORIES WILL BE EQUIPPED WITH SYSTEMS FOR ASSESSING HEMODYNAMIC SIGNIFICANCE OF CORONARY LESIONS (I.E., FFR, IFR, OR OTHER) AND INTRACORONARY IMAGING TECHNOLOGY (I.E., IVUS OR OCT) FOR ENSURING PCI OPTIMIZATION.
- (e) A WRITTEN AGREEMENT WITH AN OHS HOSPITAL THAT IS WITHIN 30 MINUTES TRAVEL TIME THAT INCLUDES ALL OF THE FOLLOWING:
- (i) INVOLVEMENT IN CREDENTIALING CRITERIA AND RECOMMENDATIONS FOR PHYSICIANS APPROVED TO PERFORM PCI PROCEDURES.
- (ii) PROVISION FOR ONGOING CROSS-TRAINING FOR PROFESSIONAL AND TECHNICAL STAFF INVOLVED IN THE PROVISION OF PCI TO ENSURE FAMILIARITY WITH INTERVENTIONAL EQUIPMENT. COMPETENCY SHALL BE DOCUMENTED ANNUALLY.
- (iii) REGULARLY HELD JOINT CARDIOLOGY/CATHETERIZATION LABORATORY CONFERENCES TO INCLUDE REVIEW OF PCI CASES.
- (iv) DEVELOPMENT AND ONGOING REVIEW OF PATIENT SELECTION CRITERIA FOR PCI PATIENTS AND IMPLEMENTATION OF THOSE CRITERIA.
- (v) A MECHANISM TO PROVIDE FOR APPROPRIATE PATIENT TRANSFERS BETWEEN FACILITIES AND AN AGREED PLAN FOR PROMPT CARE.
- (vi) WRITTEN PROTOCOLS, SIGNED BY THE APPLICANT AND THE OHS HOSPITAL, FOR THE IMMEDIATE TRANSFER FROM THE CARDIAC CATHETERIZATION LABORATORY TO EVALUATION ON SITE IN THE OHS HOSPITAL, OF PATIENTS REQUIRING SURGICAL EVALUATION AND/OR INTERVENTION 365 DAYS A YEAR. THE PROTOCOLS SHALL BE REVIEWED AND TESTED ON A QUARTERLY BASIS.
- (vii) CONSULTATION ON FACILITIES, EQUIPMENT, STAFFING, ANCILLARY SERVICES, AND POLICIES AND PROCEDURES FOR THE PROVISION OF INTERVENTIONAL PROCEDURES.

- (f) A WRITTEN PROTOCOL SHALL BE ESTABLISHED AND MAINTAINED FOR CASE SELECTION FOR THE PERFORMANCE OF PCI CONSISTENT WITH THE CASE SELECTION CRITERIA DOCUMENTED IN THE SCAI POSITION STATEMENT ON THE PERFORMANCE OF PERCUTANEOUS CORONARY INTERVENTION IN AMBULATORY SURGICAL CENTERS (BOX ET AL. CATHETER CARDIOVASC INTERV. 2020;1-9).
- (g) THE APPLICANT SHALL PARTICIPATE IN A DATA REGISTRY ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE AS A MEANS TO MEASURE QUALITY AND RISK ADJUSTED OUTCOMES WITHIN PCI SERVICES WITHOUT ON-SITE OHS SERVICES, AND THE APPLICANT SHALL IDENTIFY A PHYSICIAN POINT OF CONTACT FOR THE DATA REGISTRY.
- (h) CATH LAB FACILITY REQUIREMENTS SHALL CONFORM TO THE POSITION STATEMENT ON THE PERFORMANCE OF PERCUTANEOUS CORONARY INTERVENTION IN AMBULATORY SURGICAL CENTERS (BOX ET AL. CATHETER CARDIOVASC INTERV. 2020;1-9). THE APPLICANT SHALL BE LIABLE FOR THE COST OF DEMONSTRATING COMPLIANCE WITH THE PRINCIPLES DOCUMENTED IN THIS POSITION STATEMENT IN THEIR APPLICATION.
- (i) THE APPLICANT SHALL PROJECT THE FOLLOWING BASED ON VERIFIABLE DATA FROM THE MOST RECENT 12-MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT, AS APPLICABLE:
- (i) IF THE APPLICANT IS PROPOSING A SINGLE LAB, AT LEAST 750 PROCEDURE EQUIVALENTS TOTAL, INCLUDING AT LEAST 540 PROCEDURES EQUIVALENTS FROM ELECTIVE PCIs (200 PCI SESSIONS).
- (ii) IF THE APPLICANT IS PROPOSING MULTIPLE LABS, AT LEAST 1,000 PROCEDURE EQUIVALENTS PER LAB, INCLUDING AT LEAST 540 PROCEDURE EQUIVALENTS TOTAL FROM ELECTIVE PCIs (200 PCI SESSIONS).
- (j) THE APPLICANT SHALL HAVE OR OBTAIN WITHIN 12 MONTHS OF BEGINNING OPERATIONS AMBULATORY SURGERY CENTER (ASC) CERTIFICATION OR HOSPITAL OUTPATIENT DEPARTMENT (HOPD) STATUS FROM THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS). AN APPLICANT THAT DOES NOT CURRENTLY HOLD THE CERTIFICATION SHALL ATTEST THAT THE CERTIFICATION WIILL BE OBTAINED WITHIN 12 MONTHS OF BEGINNING OPERATIONS.

- Section 4(3): New requirements to allow for an FSOF to perform CIED procedures.
  - (3) AN APPLICANT FSOF PROPOSING TO PERFORM CIED PROCEDURES SHALL DEMONSTRATE ALL OF THE FOLLOWING:
  - (a) THE FSOF IS APPROVED TO PERFORM DIAGNOSTIC CARDIAC CATHETERIZATION AND ELECTIVE PCI OR IS APPLYING TO PROVIDE BOTH OF THOSE SERVICES AS A PART OF THIS APPLICATION.
  - (b) THE APPLICANT IS LOCATED LESS THAN 30 MINUTES TRAVEL TIME FROM A HOSPITAL WITH OHS SERVICE.
  - (c) THE APPLICANT HAS OR WILL HAVE CARDIAC CATHETERIZATION LAB CAPABILITIES INCLUDING PERICARDIOCENTESIS EQUIPMENT ON SITE.
  - (d) THE APPLICANT HAS IDENTIFIED AT LEAST ONE PHYSICIAN WHO MEETS ALL OF THE FOLLOWING:
  - (i) IS CARDIOLOGY BOARD CERTIFIED FOR PERMANENT PACEMAKER IMPLANTS;

- (ii) IS EP BOARD CERTIFIED FOR ICD IMPLANTS;
- (iii) HAS ACTIVE PRIVILEGES FOR IMPLANTING DEVICES, MODERATE SEDATION, AND ADMITTING AT THE TERTIARY CARE HOSPITAL IDENTIFIED IN (3)(b);
- (iv) HAS AT LEAST 2 YEARS OF POST-FELLOWSHIP EXPERIENCE AS AN IMPLANTER; AND
- (v) HAS IMPLANTED AT LEAST 75 DEVICES AS THE PRIMARY OPERATOR IN THE PREVIOUS 2 YEARS POST FELLOWSHIP TRAINING.
- (e) THE APPLICANT SHALL PROJECT AT LEAST 100 CIED PROCEDURES.
- (f) THE APPLICANT SHALL HAVE OR OBTAIN WITHIN 12 MONTHS OF BEGINNING OPERATIONS AMBULATORY SURGERY CENTER (ASC) CERTIFICATION OR HOSPITAL OUTPATIENT DEPARTMENT (HOPD) STATUS FROM THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS). AN APPLICANT THAT DOES NOT CURRENTLY HOLD THE CERTIFICATION SHALL ATTEST THAT THE CERTIFICATION WIILL BE OBTAINED WITHIN 12 MONTHS OF BEGINNING OPERATIONS.

- Section 6(1)(d): Added language.
  - (d) A MINIMUM OF 540 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PCI PROCEDURES.
- Section 10(2): Added criteria to the project delivery requirements for physicians credentialed by an FSOF to perform PCI.
  - (g) EACH PHYSICIAN CREDENTIALED BY AN FSOF TO PERFORM PCI SHALL MEET THE FOLLOWING CRITERIA:
  - (i) HAS PERFORMED AT LEAST 50 PCI SESSIONS ANNUALLY AS THE PRIMARY OPERATOR DURING THE MOST RECENT PRECEDING 24 MONTHS;
  - (ii) HAS COMPLETED AN INTERVENTIONAL CARDIOLOGY FELLOWSHIP TRAINING PROGRAM;
  - (iii) IS BOARD CERTIFIED IN INTERVENTIONAL CARDIOLOGY;
  - (iv) HAS PERFORMED A TOTAL OF AT LEAST 250 PCI SESSIONS AS THE PRIMARY OPERATOR; AND
  - (v) HAS A MINIMUM OF 2 YEARS EXPERIENCE AT AN ATTENDING LEVEL.
  - (h) EACH PHYSICIAN CREDENTIALED BY A FSOF TO PERFORM CIED PROCEDURES SHALL MEET THE FOLLOWING CRITERIA:
  - (i) PERFORMED AT LEAST 75 DEVICE IMPLANTS AS THE PRIMARY OPERATOR IN THE PREVIOUS 24 MONTHS;
  - (ii) HAS AT LEAST 2 YEARS OF POST-FELLOWSHIP EXPERIENCE AS AN IMPLANTER;
  - (iii) IS CARDIOLOGY BOARD CERTIFIED FOR PERMANENT PACEMAKER IMPLANTS;
  - (iv) IS EP BOARD CERTIFIED FOR ICD IMPLANTS; AND
  - (v) HAS ACTIVE PRIVILEGES FOR IMPLANTING DEVICES, MODERATE SEDATION, AND ADMITTING AT THE HOSPITAL IDENTIFIED IN SECTION 4(3)(b).
- Section 10(2): Added criteria to the project delivery requirements for a diagnostic cardiac catheterization and elective PCI program located at an FSOF.
  - (m) A DIAGNOSTIC CARDIAC CATHETERIZATION AND ELECTIVE PCI PROGRAM LOCATED AT AN FSOF SHALL OBTAIN AMBULATORY SURGERY CENTER (ASC) CERTIFICATION OR HOSPITAL OUTPATIENT DEPARTMENT (HOPD) STATUS FROM THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) WITHIN 12 MONTHS OF BEGINNING OPERATIONS AND

SHALL HAVE AT LEAST ONE INTERVENTIONAL CARDIOLOGIST ON ITS ACTIVE STAFF MEETING THE FOLLOWING CRITERIA:
  - (i) HAS PERFORMED AT LEAST 50 PCI SESSIONS ANNUALLY AS THE PRIMARY OPERATOR DURING THE MOST RECENT 24-MONTH PERIOD;
  - (ii) HAS COMPLETED AN INTERVENTIONAL CARDIOLOGY FELLOWSHIP TRAINING PROGRAM;
  - (iii) IS BOARD CERTIFIED IN INTERVENTIONAL CARDIOLOGY;
  - (iv) HAS PERFORMED A TOTAL OF AT LEAST 250 PCI SESSIONS AS THE PRIMARY OPERATOR; AND
  - (v) HAS A MINIMUM OF 2 YEARS EXPERIENCE AT AN ATTENDING LEVEL.
  - (n) AN FSOF PERFORMING CIED PROCEDURES SHALL HAVE AT LEAST ONE ELECTROPHYSIOLOGIST ON ITS ACTIVE STAFF MEETING THE FOLLOWING CRITERIA:
  - (i) IS CARDIOLOGY BOARD CERTIFIED FOR PPM IMPLANTS;
  - (ii) IS EP BOARD CERTIFIED FOR ICD IMPLANTS;
  - (iii) HAS ACTIVE PRIVILEGES FOR IMPLANTING DEVICES, MODERATE SEDATION, AND ADMITTING AT THE HOSPITAL IDENTIFIED IN SECTION 4(3)(B);
  - (iv) HAS AT LEAST 2 YEARS OF POST-FELLOWSHIP EXPERIENCE AS AN IMPLANTER; AND
  - (v) HAS IMPLANTED AT LEAST 75 DEVICES AS THE PRIMARY OPERATOR IN THE PREVIOUS 2 YEARS POST FELLOWSHIP TRAINING.
- Section 10(4)(a): Adjusted the maintenance volume requirements for hospitals in rural/micropolitan counties and added maintenance volume requirements for FSOFs. Volume requirements are in line with national guidelines to ensure quality outcomes.
  - (m) A DIAGNOSTIC CARDIAC CATHETERIZATION AND ELECTIVE PCI PROGRAM LOCATED AT AN FSOF SHALL OBTAIN AMBULATORY SURGERY CENTER (ASC) CERTIFICATION OR HOSPITAL OUTPATIENT DEPARTMENT (HOPD) STATUS FROM THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) WITHIN 12 MONTHS OF BEGINNING OPERATIONS AND SHALL HAVE AT LEAST ONE INTERVENTIONAL CARDIOLOGIST ON ITS ACTIVE STAFF MEETING THE FOLLOWING CRITERIA:
  - (i) 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures FOR A HOSPITAL IN A METROPOLITAN COUNTY.
  - (ii) 150 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES FOR A HOSPITAL IN A RURAL OR MICROPOLITAN COUNTY.
  - (v) 250 procedure equivalents for a hospital in a rural or micropolitan county with one laboratory.
  - (vi) 750 procedure equivalents for a hospital in a metropolitan county OR AN FSOF with one laboratory.
  - (ix) 200 adult PCI procedures for an elective PCI service without on-site OHS service LOCATED IN A HOSPITAL OR FSOF.
  - (x) 100 CIED PROCEDURES FOR AN FSOF PROVIDING CIED SERVICES.
- Section 10(5)(g): Added project delivery requirements for diagnostic cardiac catheterization and elective PCI services at an FSOF.
  - (g) FOR DIAGNOSTIC CARDIAC CATHETERIZATION AND ELECTIVE PCI SERVICES AT AN FSOF, CATHETERIZATION LAB FACILITY REQUIREMENTS SHALL CONFORM TO THE POSITION STATEMENT ON THE PERFORMANCE OF PERCUTANEOUS CORONARY INTERVENTION IN AMBULATORY SURGICAL

CENTERS (BOX ET AL. CATHETER CARDIOVASC INTERV. 2020;1-9). THE APPLICANT FACILITY SHALL BE LIABLE FOR THE COST OF DEMONSTRATING COMPLIANCE WITH THE PRINCIPLES DOCUMENTED IN THIS POSITION STATEMENT.

- Section 10(6): Added project delivery requirements for FSOFs providing CIED procedures.
  - (6) COMPLIANCE WITH ALL OF THE FOLLOWING REQUIREMENTS FOR FSOFS PROVIDING CIED PROCEDURES:
  - (a) MAINTAIN A WRITTEN TRANSFER AGREEMENT AND PROTOCOLS WITH THE TERTIARY CARE CENTER IDENTIFIED IN SECTION 4(3)(b).
  - (b) MAINTAIN CARDIAC CATH LAB CAPABILITIES INCLUDING PERICARDIOCENTESIS EQUIPMENT ON SITE.
  - (c) REPORT ACUTE OUTCOMES OF PROCEDURES TO A REGISTRY IDENTIFIED BY THE DEPARTMENT.
  - (d) MAINTAIN DEVICE FOLLOW UP PROTOCOLS.
- Section 10(6): Added project delivery requirements for FSOFs providing CIED procedures.
  - (6) COMPLIANCE WITH ALL OF THE FOLLOWING REQUIREMENTS FOR FSOFS PROVIDING CIED PROCEDURES:
  - (a) MAINTAIN A WRITTEN TRANSFER AGREEMENT AND PROTOCOLS WITH THE TERTIARY CARE CENTER IDENTIFIED IN SECTION 4(3)(b).
  - (b) MAINTAIN CARDIAC CATH LAB CAPABILITIES INCLUDING PERICARDIOCENTESIS EQUIPMENT ON SITE.
  - (c) REPORT ACUTE OUTCOMES OF PROCEDURES TO A REGISTRY IDENTIFIED BY THE DEPARTMENT.
  - (d) MAINTAIN DEVICE FOLLOW UP PROTOCOLS.
- Section 10(6): Added project delivery requirements for FSOFs providing CIED procedures.
- Other technical edits.

The following review standards were reviewed with an anticipated completion in FY2022:

Hospital Beds: Proposed action was taken by the Commission at its September 16, 2021 meeting. The standards were submitted to the joint legislative committee (JLC) and a Public Hearing was held. The Commission is scheduled to take final action at its December 9, 2021 Commission meeting, and the standards will become effective in FY2022.

Positron Emission Tomography (PET) Scanner Services: Proposed action was taken by the Commission at its September 16, 2021 meeting. The standards were submitted to the JLC and a Public Hearing was held. The Commission is scheduled to take final action at its December 9, 2021 Commission meeting, and the standards will become effective in FY2022.

Magnetic Resonance Imaging (MRI) Services is being reviewed by an informal workgroup.

Psychiatric Beds and Services is being reviewed by an informal workgroup.

PET Scanner Services is scheduled to be reviewed by a standard advisory committee (SAC).

APPENDIX I - CERTIFICATE OF NEED COMMISSION

Amy McKenzie, MD, CON Commission Chairperson
James B. Falahee, Jr., JD, CON Commission Vice-Chairperson
Justin B. Dimick, MD
Amy Engelhardt-Kalbfleisch, DO
Eric Ferguson, MD succeeded Melissa Oca, MD
Debra Guido-Allen, RN
Donald Haney succeeded J. Lindsey Dood
Ashok Kondur, MD
Melanie Lalonde
Lorissa MacAllister, PhD
Renee Turner-Bailey succeeded Thomas Mittlebrun, III

For a list and contact information of the current CON Commissioners, please visit our web site at **http://www.michigan.gov/con**.